2001. The survey focused on a subset of applied articles in English, after excluding methodological, environmental or veterinarian studies, and those not reporting cost data. Finally, articles employing MCS for purposes other than conducting PSA were excluded. Descriptive analyses were used to evaluate their methods.
RESULTS: Of the 319 articles identified, 39 met the inclusion/exclusion criteria. Of these 39 studies, 64% were published after 1998. PSA was commonly used to reflect uncertainty regarding probabilities or costs, but less commonly for utilities. When applicable, the distribution type was specified for 42%, 56%, and 64% of utility, cost, and probability parameters, respectively. Sixty-one percent of studies used uniform, triangular or normal distributions. Justification for the distribution type was inconsistently reported. Only 8% of studies assumed some correlation between parameters or presented absolute worst- or best-case scenarios, which theoretically bound all possible simulation results. Over 70% of studies used acceptability thresholds or curves for reporting cost-effectiveness results.
CONCLUSIONS: Our survey indicates that the use of PSA is increasingly popular. However, how these methods have been applied has rarely been sufficiently transparent. PSA is relatively new in health economics and studies employing this technique should provide transparent descriptions of their methods. This will improve the acceptability and usefulness of PSA, while providing guidance to analysts wishing to use this powerful methodology.

PMI33

LITERATURE REVIEW OF GUIDELINES FOR CROSS-CULTURAL ADAPTATION OF HRQL MEASURES: UPDATED RESULTS

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In response to European regulators' concern about the methodology followed to translate and achieve cultural adaptation of Health-related Quality of Life (HRQL) instruments (i.e. the process of adapting a measure from a source to a target language), the ERIQA Group has integrated the development of regulators-targeted guidance documents for cross-cultural adaptation into their programme. The first step in collaboration with Mapi Research Institute has been to investigate current guidelines.
OBJECTIVES: To identify and analyse the methods used for cultural adaptation of HRQL instruments.
METHODS: Medline and Embase were searched using the keywords "quality of life", "questionnaires", "health status indicators" which were matched with "translating" and "cross-cultural comparison". Papers published between January 1966 and April 2001 were taken into consideration. 173 references were identified. Mapi Research Institute's database was searched using "translation issues", "cross-cultural comparison", and "cross-cultural research", with 236 references as a result. 409 abstracts were reviewed. Inclusion criteria were: 1) the paper should propose guidelines/recommendations or 2) it should review and analyse methods.
RESULTS: 32 papers met with the inclusion criteria. 14 sets of guidelines were identified. A lack of consensus emerged about: a) the terminology qualifying the process of adapting a HRQL instrument from source to target language, and b) the scope covered by this terminology. Similarities included multiple forward translations, reconciliation sessions, and some form of back-translations. Differences appeared in the importance given to back-translation, forms of panel testing, and translators' recruitment criteria. Few articles compared methodologies.
CONCLUSION: This review shows disparity in definitions and methods. Further investigations may be needed in order to explore empirical evidence of the methods' effectiveness, and propose recommendations for regulators.

PMI34

A LOGICAL PROBLEM IN VIEWING UTILITY THEORY AS NORMATIVE

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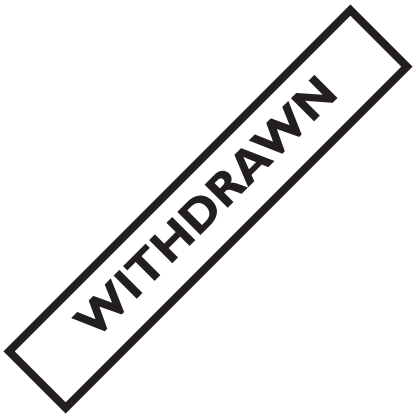
OBJECTIVES: Evaluate the claim that Utility Theory (UT) is normative.
METHODS: Logical analysis of UT and normative injunctions. The positive/normative distinction is between "is" and "ought." Positive statements describe how things are; normative injunctions (e.g., "First, cause no harm") request that we act in certain ways. The normative interpretation of UT suggests that we should act so as to maximize our utility.
RESULTS: The normative interpretation of UT leaves the individual with a decision to make: "Should I act so as to maximize my utility?" If the individual applies UT as a decision procedure to answer this question, then an affirmative answer to the question is being assumed and not proved. Alternatively, the individual could attempt to justify the use of UT by appealing to a more general decision procedure. But if the more general decision procedure can decide this question, then why use UT at all? The more general decision procedure could be used in the place of UT to decide everyday questions. But, then, the more general decision procedure requires justification. To justify its use, we must appeal to an even more general decision procedure. So, we embark upon an infinite regress when trying to justify UT by appealing to more general decision procedures. The logical problem with the normative view of UT does not carry over to medical decision making in general, where an external criterion is used as an indicator for a particular characteristic. Vis a vis medical decision making, the logical problem with the

normative view of UT derives from its universal sweep and consequent lack of an external criterion.
CONCLUSIONS: The normative interpretation of UT leads to circular reasoning or an infinite regress, forcing the recognition that the normative aspect of UT lies in the decision to apply UT, not in UT per se.

PMI35



PMI36

INCORPORATING JAPAN INTO GLOBAL OUTCOMES RESEARCH PROTOCOLS

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Simultaneous global pharmaceutical development, registration and outcomes research (OR) strategies are now commonplace. However, incorporating Japan into global OR plans is a challenge.
OBJECTIVE: This paper addresses the concerns of global OR researchers by presenting a systematic approach to incorporating Japan into global research protocols and strategies.
METHODS: Informal interviews with managers involved in global R&D or OR planning and a literature review of pharmacoeconomic studies was conducted. Based on knowledge gained from several years of actual experience conducting outcomes research in Japan, these information sources were synthesized into a recommended approach for incorporating Japan into global OR plans.
RESULTS: 39 published studies were found in the Japanese and English literature from 1980–2001, however, no mention of global research protocols was found. Based on interviews three activities were recommended to effectively incorporate Japan into global OR plans/protocols: 1) a Japan OR expert should first review draft global OR plans/protocols and prospectively identify critical success factors in Japan, then 2) Japan OR expert should draft Japan plans/protocols, and 3) establish a strong feedback loop from global OR to the Japan OR expert to incorporate Japan input in global plans/protocols. Critical success factors in Japan include: 1) academic expert assistance; 2) feasibility assessment; 3) institutional commitment; 4) strategic fit with Japan. Building draft Japan plans/protocols requires a preliminary assessment of Japan's medical environment: 1) clinical practice; 2) epidemiology; 3) political, sociological, ethnic and health care financing issues; 4) regulatory issues. Establishing a strong communication link between Japan and global OR will ensure that the Japan plans are integrated into the global OR plans/protocols.
CONCLUSION: Global outcomes research plans/protocols must incorporate Japan. Working with a Japan OR expert is highly recommended so that global research plans adequately reflect an awareness of critical success factors and the local medical environment in Japan.

PMI37

INTEGRATION OF INTERNATIONAL INPUT INTO INSTRUMENT DESIGN: TRANSLATABILITY ASSESSMENT

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OBJECTIVES: The last 20 years have seen the development of numerous PRO measures mostly however within and for one culture. Based on the assumption that the original concepts are universally appropriate, instruments destined for international use are translated following a standardized procedure (linguistic validation). This process however reveals the interdependence of translation and original and the importance of integrating an international component into the design of instruments, which can be done through a Translatability Assessment. The presentation will illustrate the methodology and the advantages of this new approach.
METHODS: A translatability assessment can be defined as an international critical review of a pre-final original in collaboration with the developer. In the absence of international development, this may be a cost and time effective compromise between the WHO approach to instrument development and translation. The translation process usually reveals difficulties when adapting the format, instructions, concepts, idiomatic expressions, response scales or demographic items to different languages. The translatability assessment proposes to review these aspects and suggest re-formulations in the original considering the context and constraints of other languages/cultures.
RESULTS: Several examples of the impact of the Translatability Assessment on the original wording will be given. For instance, although the term "work" in English